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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,386	07/19/2000	BERND FABRY	H-3190-PCT/U	2052

23657 7590 07/13/2004

COGNIS CORPORATION
PATENT DEPARTMENT
300 BROOKSIDE AVENUE
AMBLER, PA 19002

EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/13/2004

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,386

Applicant(s)

FABRY, BERND

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 3/27/04 has been entered.

Claims 11-30 are pending and rejected. No claim is allowed.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 11-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-30 of copending Application No. 09/554,387. Although the conflicting claims are not identical, they are not

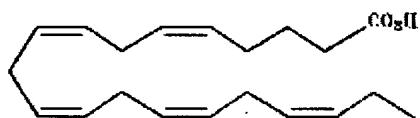
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patentably distinct from each other because presently claimed invention is drawn to method of reducing serum cholesterol content in mammals by providing a composition of phytosterol ester composition, which is considered obvious over the claimed invention of the said copending application.

3. No significant difference was found between these claimed inventions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Structure of the EPA, DHA, phytosterol esters (conjugated fatty acid).



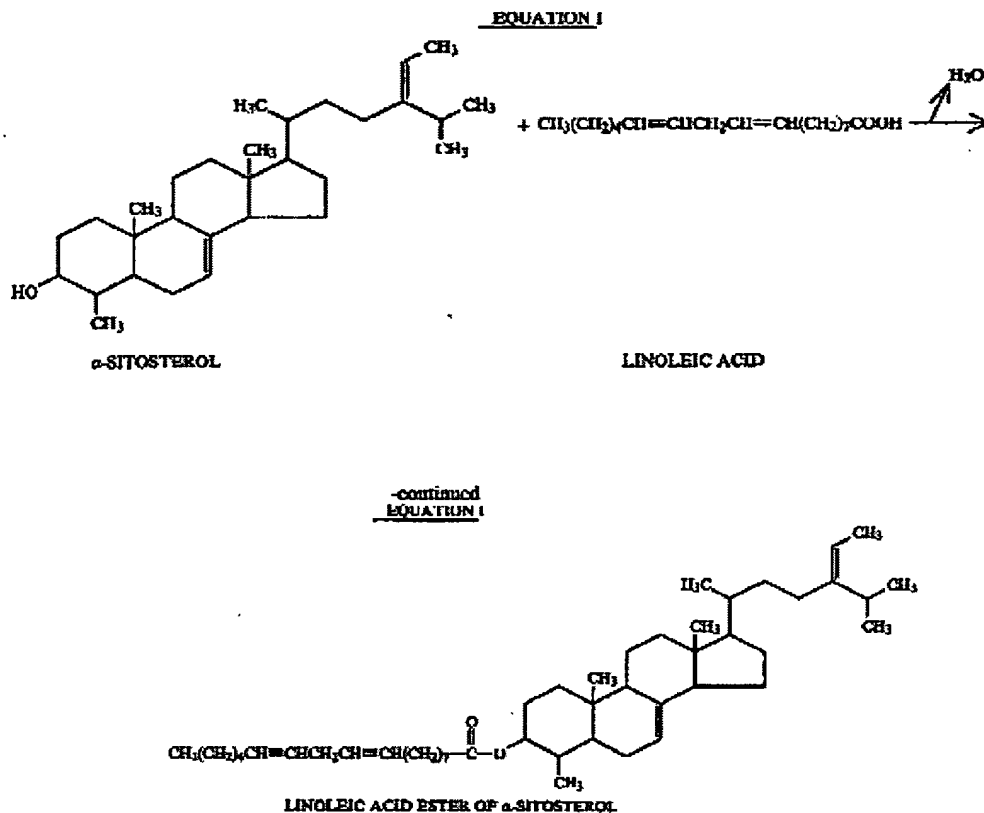
EPA



DHA

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Phytosterol ester



1. Claims 11-30 are rejected under 35 U.S.C. 103(a) as obvious over Mitchell (US Patent 4,588,717), Kamarei et al. (US Patent 4,879,312) and Miettinen et al. (WO 92/19640). See the entire documents especially lines 1-33, col. 7; col. 1-37, col. 8, equation 1 and examples in US '717; lines 39-59, col. 2 in US '312 and lines 22-30, page 9 and lines 20-24, page 10; lines 4-6, page 5; lines 8-37, page 6 in WO '640.

1. **Determining the scope and contents of the prior art.**

Prior art teaches a composition which embraces applicants claimed invention.

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Mitchell teaches vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigma sterol and taxasterol, in various combinations. Fatty acid have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups (lines 2-15, col. 6) and at least two double bonds such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters, (see lines 21-58, col. 3; lines 43-65, col. 5; equation 1 and lines 1-11 in col. 8). Furthermore, it teaches that the reaction between any given phytosterol and any given fatty acid is essentially the same, and is characterized in equation 1 using sitosterol and linoleic acid as an exemplary fatty acid.

Miettinen et al. teaches a composition of b-sitostanol fatty acid ester mixture or fatty acid ester mixture. It teaches that physical properties of mixture can be modified easily by altering the fatty acid composition of the mixture. In addition to this, the fatty acid composition of the b-sitostanol fatty acid can also be selected so as to contain large amounts of monoenes and polyenes, whereby efficacy in lowering the cholesterol levels in serum are enhanced. See lines 22-30 on page 9. The reference also teaches fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol.

Kamarei et al. teach that a diet rich in omega-3-fatty acids has beneficial effects in humans, including a reduction in plasma cholesterol and triglyceride levels, improved fat tolerance, prolonged bleeding time reduce platelet counts and decreased platelet adhesiveness. The omega-3-fatty acids are obtained mainly from dietary seafood. It teach n-3 Poly unsaturated fatty acids (PUFA) participation and reasons why these materials may be involved in alleviating ischemic heart diseases. Furthermore, it also teaches that one of n-3 PUFA i.e. eicosapentaenoic acid (EPA) and DHA reduces triglyceride and very low-density lipoprotein (VLDL) serum levels

and reduces whole blood viscosity. (See lines 39-59, col. 2; lines 13-54, col. 3; Table 1 and 2 in col. 4).

2. Ascertaining the differences between the prior art and the claims at issue.

Prior art teaches compounds with fatty acids especially containing approximately 2-22 carbon atoms (lines 20-24, page 10). Instant claim is a selection of prior art teachings as EPA and DHA contain 20 and 22 carbons respectively which is taught by the prior art, see lines 20-25 on page 10 of WO '640 and US '717.

Instant claims are the generically of the prior art teachings.

3. Resolving the level of ordinary skill in the pertinent art.

Therefore, it would be obvious to one skilled in the art at the time of invention to employ phytosterols composition in combination with omega-3-fatty acids and methods for lowering cholesterol and triglycerides in blood stream of a subject, because these agents are known individually for the treatment of the same disorders. See example 4 on page 11 of WO '640, where other oils such as sunflower, soybean olive and corn oil can also be used, which contain EPA and DHA. All the ingredients of the instant invention are taught by the prior art for the same use.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The combination of agents, each of which is known for the same purpose, is considered *prima facie* obvious. At least additive therapeutic results would be expected. See *In re Kerkhoven* 205 U.S. P.Q. 1069.

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Motivation is to prepare additional beneficial composition of sterols with unsaturated fatty acids such as omega-3-fatty acids, EPA, DHA, useful for lowering the cholesterol and triglyceride levels, because this use has been taught by the prior art for the said compositions. Preparation of supplemental vitamins, margarine and mayonnaise is taught by the prior art cited above.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

2. Claim(s) 11-30 are rejected under 35 U.S.C. 103 as being unpatentable over combined teachings of Miettinen et al. (WO 92/19640) and Mitchell (US 4,588,717). Mitchell (US Patent 4,588,717) teaches vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigmasterol and taxasterol, in various combinations, a composition of the phytosterols, such as sitosterol, stigmasterol, taraxasterol etc reacted with linoleic acid, (18-carbons, two double bonds), linolenic acid (18-carbons, 3-double bonds), arachidonic acid (20-carbons, two double bonds). Fatty acid have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups (lines 2-15, col. 6) and at least two double bonds such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters, (see lines 21-58, col. 3; lines 43-65, col. 5; equation 1 and lines 1-11 in col. 8). Furthermore, it teaches that the reaction between any given phytosterol and any given fatty acid is essentially the same, and is characterized in equation 1 using sitosterol and linoleic acid as an exemplary fatty acid.

Miettinen et al. teaches a composition of b-sitostanol fatty acid ester mixture or fatty acid ester mixture. It teaches that physical properties of mixture can modified easily by altering the

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fatty acid composition of the mixture. In addition to this, the fatty acid composition of the b-sitostanol fatty acid can also be selected so as to contain large amounts of monoenes and polyenes, whereby efficacy in lowering the cholesterol levels in serum are enhanced. See lines 22-30 on page 9. The reference also teaches fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol which is instantly claimed. See the entire documents especially lines 22-30, page 9 and lines 20-24, page 10; lines 4-6, page 5; lines 8-37; page 6 in WO '640.

Instant claims differ from the reference in claiming reaction of phytosterol with specific fatty acids i.e. docosahexaenoic acid and eicosahexaenoic acid where as prior art teaches reaction product of phytosterol with fatty acids especially containing approximately 2-22 carbon atoms. Instant claims are a selection of prior art teachings.

It would have been obvious to one skilled in the art to prepare additional beneficial composition by selecting any fatty acids acid from fatty acid 2-22 carbon atoms taught by the prior art. There has been ample motivation provided by the prior art to prepare the instant invention. Instant compositions would have been obvious at the time of invention. The subject as instantly claimed would have been obvious to one at the time of invention.

Normally, change in temperature, concentration, or both, is not a patentable modification; however, such changes may impart patentability to a process if the ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art; more particularly, where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al.

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105 USPQ 233.

It is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

It is a general rule that merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable. Nor can patentability be found in differences in ranges recited in the claims. When the difference between the claimed invention and the prior art is some range or other variable within the claims, the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range. In re Woodruff, 16 USPQ2d 1934.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571)-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/12/04



SABIHA QAZI, PH.D
PRIMARY EXAMINER